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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,865	02/02/2001	Carl G. Hellerqvist	22100-0100 (46126-252687)	7056
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KILPATRICK STOCKTON LLP SUITE 2800 1100 PEACHTREE STREET ATLANTA, GA 30309-4530				
EXAMINER RAWLINGS, STEPHEN L.				
ART UNIT 1642		PAPER NUMBER		

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,865

Applicant(s)

HELLERQVIST, CARL G.

Examiner

Stephen L. Rawlings, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-16, 29-38, and 40-56 is/are pending in the application.
- 4a) Of the above claim(s) 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-16, 29-38, 40-48, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The response filed November 26, 2004 has been entered.
2. Claims 1, 4-16, 29-38, and 40-56 are pending in the application. Claims 49-54 have been withdrawn from further consideration pursuant to 37 CFR § 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed June 21, 2002.
3. Claims 1, 4-16, 29-38, 40-48, 55, and 56, insofar as the claims are drawn to elected invention, are currently under prosecution.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Ground of Rejection Maintained

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 4-16, 29-38, 40-48, 55, and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At pages 8-12 of the response filed November 26, 2004, Applicant has traversed this ground of rejection.

Applicant's arguments have been carefully considered but not found persuasive for the following reasons:

The factors that have been considered in determining whether undue experimentation is required are summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). These factors include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of

working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

Upon careful consideration of these factors used to determine whether undue experimentation is required, a preponderance of factual evidence of record indicates that the amount of guidance, direction, and exemplification disclosed in the specification would be insufficient to enable the skilled artisan to use the claimed invention without undue experimentation.

At page 8 of the response, Applicant has again argued that human testing is not required to obtain a patent. Again, while Applicant is indeed correct, Applicant's argument is not persuasive for the reasons set forth in the previous Office action.

Beginning at page 8 of the response, Applicant has argued that the teachings of Gura are irrelevant, since that reference "deals primarily with screening of large numbers of cell-killing compounds in order to identify cancer drugs" (paragraph bridging pages 8 and 9). The Examiner, however, disagrees; as stated in the previous Office actions, Gura teaches that the art is unpredictable and that one cannot determine reliably and accurately determine the efficacy of any particular anticancer therapy for use in humans by testing the efficacy of the candidate therapeutic agent or treatment regimen using cell lines and experimental animals.

At page 9 of the response, Applicant has asserted that later studies have superseded the teachings of Gura by providing improved mouse models, citing Wilkinson et al. (2001) in support. The Examiner disagrees with the assertion that later studies have "superseded" the teachings of Gura; despite any recent technological advance, the skilled artisan still cannot reliably and accurately predict the outcome of using candidate therapeutic agents and treatment regimens in humans by extrapolation from preliminary studies that measured their efficacy in cell lines and animal models. Furthermore, regarding the citation of Wilkinson et al. in support of Applicant's assertion, Applicant is reminded that supporting documents published after the filing date sought cannot be relied upon to correct the deficiencies of the specification by supplying the necessary and essential teachings, guidance, and exemplification that the specification lacks. See MPEP § 2164.05(a).

At page 9, Applicant has cited additional references to arguably show that "in the field of anti-cancer vaccines, mouse models are widely [...] considered reasonably predictive of the vaccines' future therapeutic utility" (page 9, paragraph 2); however, the teachings of these additional references cannot be relied upon to compensate for the insufficiency of the supporting disclosure to enable the skilled artisan to use the claimed invention, because each was published after the filing date sought by Applicant in this application.

Beginning at page 9, Applicant has again addressed *In re Brana*, 34 USPQ 1436 (CA FC 1995). Applicant has argued that this and other case law supports Applicant's position that the supporting disclosure would be found reasonably enabling of the claimed invention, since "[d]ata from in vitro or animal testing is generally sufficient to support therapeutic utility" (page 9, paragraph 3). In this instance, however, a preponderance of factual evidence of record indicates that the amount of guidance, direction, and exemplification provided in the specification would not reasonably enable the skilled artisan to use the claimed invention without undue experimentation, and so therefore the supporting disclosure fails to meet the enablement provision of 35 U.S.C. § 112, first paragraph.

At page 10 of the response, Applicant has incorrectly argued the Office's position. In the paragraph bridging pages 5 and 6, the Office action mailed July 26, 2004, states the following:

Notably, the situation faced by Applicants in the course of the instant prosecution is not analogous to that faced by Brana et al. (*In re Brana*, 34 USPQ2d 1436, CAFC 1995), since notably Applicant has not established the clinical utility of the claimed invention, nor have Applicants provided a reasonably correlative study suggesting the potential utility of the claimed invention. In the present regard, it is not merely a question of whether or not a favorable comparison of the claimed invention and proven effective antitumor therapeutic compounds implicitly asserts that the invention is also highly effective against cancer, or whether such a disclosure can be reasonably extrapolated to reliably predict the efficacy of the claimed invention encompassing clinical application. Again, the factors, which have been considered in determining whether undue experimentation would be required, have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). [...] [T]he quantity and type of experimentation that would be required before the claimed invention might be practiced with a reasonable expectation of success in view of such factors is considered undue. In contrast to the situation faced by Brana et al., in order to practice the claimed invention in this instance, the skilled artisan would not merely be required to perform routine experimentation using conventional methodology to determine optimally safe and effective dosages and schedules for administration. Contrary to the situation faced by Brana et al., in this instance, there does not appear to be a reasonable presumption of the utility of the claimed invention.

Again, the Office recognizes that clinical trials are not a requisite; but again, in this situation, one skilled in the art would *not merely have to* determine the optimally safe and effective dosages and schedules to use the claimed invention and in fact would have to perform undue experimentation before using the claimed invention, because it would first be necessary to determine whether and how the claimed invention can be used to prevent pathological conditions in mammals.

Beginning at page 10 of the response, it appears that Applicant has argued that suppression of tumor growth in mice is equivalent to prevention; the Examiner disagrees. Despite suppressing tumor growth, Fu et al. (*Clinical Cancer Research* 7: 4182-4194, 2001) provides factual evidence that the particularly claimed invention cannot be used to prevent cancer in mice; see the entire document, particularly Figure 6 at page 4192.

In summary, a careful analysis of the factors used to determine whether undue experimentation is required in view the factual evidence of record indicates that the amount of guidance, direction, and exemplification disclosed in the specification is not sufficient to enable the skilled artisan to use the claimed invention without undue experimentation.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. This application contains claims 49-54 are drawn to an invention nonelected with traverse in the paper filed June 21, 2002. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action. See 37 CFR § 1.144 and MPEP § 821.01.

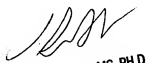
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
February 22, 2005



LARRY R. HELMS, PH.D
PRIMARY EXAMINER